DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4021. Misbranding of acetylsalicylic acid tablets, ophthalmic ointment, potassium iodide tablets, and rhinitis tablets. U. S. v. 4 Cartoned Bottles, etc. (F. D. C. No. 34671. Sample Nos. 36592–L, 70132–L to 70136–L, incl.)

LIBEL FILED: February 18, 1953, Southern District of Ohio.

ALLEGED SHIPMENT: Between August 22 and December 30, 1952, by Eli Lilly & Co., from Indianapolis, Ind.

PRODUCT: 4 cartoned bottles of 1 grain *acetylsalicylic acid tablets*, 133 cartoned bottles of 5 grain *acetylsalicylic acid tablets*, 22 cartoned tubes of *ophthalmic ointment*, 34 bottles of *potassium iodide tablets*, and 4 bottles of *rhinitis tablets* at Dayton, Ohio.

LABEL, IN PART: (Bottle) "100 Tablets * * * A. S. A. (Acetylsalicylic Acid, Lilly) 1 gr. (0.065 Gm.) * * * Dose—1 tablet as directed by the physician" and "Tablets * * * A. S. A. (Acetylsalicylic Acid, Lilly) 5 grs. (0.325 Gm.) * * * Adult Dose—1 to 3 tablets as directed by the physician"; (tube) "⅛ Ounce Ophthalmic Ointment * * * Atropine Sulfate 1 percent To be used as directed by the physician"; (bottle) "100 * * * Enseals (Timed Disintegrating Tablets, Lilly) Potassium Iodide 5 grs. (0.325 Gm.) * * * Adult Dose—1 or 2 'Enseals' as directed by the physician. Indiscriminate use may be dangerous" and "1000 Tablets * * * Rhinitis Full Strength * * * Each tablet contains: Camphor_____ ½ gr. : 0.0325 Gm. Quinine Sulfate_____ ½ gr. : 0.0325 Gm. Ext. Belladonna Root_____ ⅛ gr. : 0.0035 Gm. (Total Alkaloids, 1/960 gr.) Camphor being volatile, the exact quantity cannot be guaranteed. Adult Dose—1 or 2 tablets as directed by the physician. Indiscriminate use may be dangerous."

NATURE OF CHARGE: *Acetylsalicylic acid tablets* (1 grain and 5 grains), *potassium iodide tablets*, and *rhinitis tablets*. Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use.

Rhinitis tablets. Misbranding, Section 502 (a), the label designation "Tablets * * * Rhinitis" was false and misleading since such designation represented and suggested that the article was an adequate and effective remedy for rhinitis, whereas it was not an adequate and effective remedy for rhinitis.

Ophthalmic ointment. Misbranding, Section 503 (b) (4), the article was a drug subject to Section 503 (b) (1) (B), and the label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: March 21, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4022. Misbranding of methyltestosterone tablets, thyroid tablets, dextro-amphetamine sulfate tablets, methamphetamine hydrochloride tablets, and tablets containing a mixture of phenobarbital and mannitol hexanitrate. U. S. v. Rice M. Reavis, Jr. Plea of nolo contendere. Fine, $350. (F. D. C. No. 33709. Sample Nos. 16316–L, 16317–L, 16321–L, 16323–L to 16325–L, incl., 16327–L.)

INFORMATION FILED: October 16, 1952, Eastern District of Oklahoma, against Rice M. Reavis, Jr., a partner in the partnership of the Reavis Drug Co., Ardmore, Okla.

*See also No. 4021.